

Remarks/Arguments:

Status of Claims

Claims 15, 16, 39-54 and 81-107 are in the application.

The Detailed Action of the Official Action indicates that all previous rejections are moot, that claim 92 was objected to under 37 CFR 1.75, and that claims 15, 16, 39-54 and 81-107 are rejected under the judicially created doctrine of obviousness type double patenting and that claims 15, 16, 39-43, 45-49, 51-53, 81, 83, 85, 87, 89-91, 93, 95-97, 99 and 101 have been rejected under 35 U.S.C. §103(a) and that the action is final.

By way of this amendment, claim 92 has been canceled.

Upon entry of this amendment, claims 15, 16, 39-54, 81-91 and 93-107 will be pending.

Summary of the Amendment

Replacement pages have been provided to substitute a new set of drawings. The subject matter on the substitute pages contain no new matter.

Claim 92 has been canceled as being identical in scope to claim 88.

Request Finality be Withdrawn as Premature

Applicants note the rejection of claims 15, 16, 39-43, 45-49, 51-53, 81, 83, 85, 87, 89-91, 93, 95-97, 99 and 101 under 35 U.S.C. §103(a) were modified in view of Applicant's amendment and that the Amendment necessitated the grounds of rejection. Claims 15, 16, 39-43, 45-49, 51-53, 81, 83, 85, 87, 89-91, 93, 95-97, 99 and 101 under 35 U.S.C. §103(a) Applicants urge that the amendment of claim 15 did not necessitate the new ground for rejection. The amendment of claim 15 in the previous reply deleted certain embodiments. The subject matter in the claim as pending was present in claim 15 and the new grounds for rejection could have been applied to the claim in the earlier official action. Applicants amendment did not necessitate the new rejection and it was improper to make the action final. Applicants respectfully request that the finality of the rejection be withdrawn.

Claim Objection

Claim 92 has been objected to as being a substantially duplicate of claim 88. Claim 92 has been canceled and the objection is moot.

Double Patenting

Claims 15, 16, 39-54 and 81-107 have been rejected over the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-4 and 7 of U.S. Patent No. 6,348,449. Applicants note that the obvious-type double patenting rejection is the only rejection made to claims 44, 50, 54, 82, 84, 86, 88, 94, 98, 100 and 104-107. Provided herewith is a terminal disclaimer to obviate the obvious-type double patenting rejection.

Claim Rejection – 35 USC §103

Claims 15, 16, 39-41, 45-47, 51, 81, 83, 85, 87, 89, 93, 95, 99 and 101 have been rejected under 35 USC 103(a) as being unpatentable over Carson et al. (US Patent No. 5,679,647) in view of Gately et al (Cell Immunol 1992; 143:127-42) and as evidenced by Carson et al. (US Patent No 5,804,566) and the Webster's English Dictionary.

It is asserted that Carson et al. ('647) teach a method of inducing an immune response against an antigen by delivery of a plasmid to mucosal tissue including mouth. It is noted in the Official Action that Carson et al ('647) does not use the term "sublingual." The Official Action refers to a Webster's dictionary definition of sublingual as "situated or administered under the tongue." (Official Action, page 5). It is asserted that mouth and sublingual refer to the same route of administration. Carson et al ('566) is cited as listing routes of administration including "sublingual, oral, inhalation and nasal" as evidence that sublingual is a well known route of administration. Gately et al. refers to IL-12 and its activity with respect to the immune system. It is asserted that that it would be obvious to modify the teachings of Carson et al ('647) with those of Gately et al. by selecting a known route of administration such as sublingual or buccal for vaccination and including IL-12 in the vaccine. Applicants respectfully disagree.

Applicants respectfully urge that the art teaches away from the claimed invention and those skilled in the art would not have produced a method of inducing an immune response using a sublingual route of administration.

Carson et al. ('566) supports Applicants position. Carson et al. ('566) lists sublingual separately from oral route of administration demonstrating that sublingual is different from oral just as, Applicants urge, sublingual is different from mouth. Applicants urge that the assertion that sublingual is a reasonable alternative to mouth is without merit.

Carson et al. ('566) teaches that mucosal routes are less effective than intradermal for delivering DNA to modulating mucosal immune responses. Carson et al. ('566) teaches away from the present invention and those skilled in the art viewing Carson ('566) would not be motivated to use the sublingual route. Those skilled in the art viewing Carson ('566) would conclude that a route other than the sublingual route should be used. Carson ('647) does not list sublingual. In view of Carson ('566), one skilled in the art would not be motivated to use sublingual route of administration and would reasonably conclude that sublingual administration should not be used.

Applicants respectfully request that the rejection of claims 15, 16, 39-41, 45-47, 51, 81, 83, 85, 87, 89, 93, 95, 99 and 101 under 35 U.S.C. 103(a) as being unpatentable over Carson et al. ('647) in view of Gately et al and as evidenced by Carson et al. ('566) and the Webster's English Dictionary be withdrawn.

Claims 42, 43, 48, 52, 53, 90, 91, 96, 97, 102 and 103 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Carson ('647 and '566) and Gately et al. as applied to claims 15, 16, 39-41, 45-47, 51, 81, 83, 85, 87, 89, 93, 95, 99, 101 and further in view of Wang et al. (PNAS 1993:41656-60).

The teachings of Carson et al. ('647), Carson et al. ('566) and Gateley et al. are discussed above.

Wang discloses administration of a plasmid encoding HIV gp160 in an HIV vaccine.

It is asserted that it would have been obvious to combine the teachings of Carson et al. ('647), Carson et al. ('566), Gateley et al. and Wang for developing a vaccine against HIV gp160. It

is asserted that one skilled in the art “would have been motivated to modify the claimed invention because the mucosal route requires less amount of antigen for inducing an effective immune response.”

Applicants respectfully disagree. As noted above, Carson et al. ('647) and Gately et al. in view of Carson ('566) teaches away from sublingual administration. Nothing in Wang makes up for this deficiency. The combination of Carson et al. ('647), Carson ('566) and Gately et al. in view of Wang do not render the claimed invention obvious.

Applicants respectfully request that the rejection of claims 42, 43, 48, 52, 53, 90, 91, 96, 97, 102 and 103 under 35 U.S.C. §103(a) as being unpatentable over Carson ('647 and '566) and Gately et al. and further in view of Wang et al. be withdrawn.

Drawings

The Official Action indicates that new corrected drawings are required because the drawings of record are “hand-written informal drawings.” It is asserted that a failure to provide corrected drawings will result in abandonment of the application. No PTO-948 Form was provided in the instant Office Action or the previous Office Action. No reason for requiring corrected drawings was offered in the previous Office Action. Applicants note that the Office no longer makes the distinction between formal and informal drawings and it is only proper to require corrected drawings if the drawings are deemed unacceptable. No such reasons have been given.


Provided herewith are replacement pages with substitute figures. Although no reasons were given why the original drawings were unacceptable, Applicants provide herewith a new set of drawings in a bona fide attempt to ensure that that application contains acceptable drawings.

Conclusion

Claims 15, 16, 39-54, 81-91 and 93-107 are in allowable form. The rejections of the claims under 35 U.S.C. §103 should be withdrawn. The finality of the rejection should be withdrawn. The amendment places the claims in better condition for appeal without raising new issues for appeal and should be entered. An indication that the claims are allowable is earnestly solicited.

Respectfully submitted,

Dated Feb 23, 2005
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Attachments: Replacement pages with substitute drawings
Terminal Disclaimer

Application Serial No.: 10/076,900

UPAP0003-100 (136622)

Response to Official Action dated August 23, 2004

Amendment After Final Rejection and Reply dated February 23, 20052003

Amendments to the Drawings:

Pursuant to 37 CFR 1.121(d) replacement pages are provided herewith which contain substitute drawings.